

National Toxic Encephalopathy Foundation

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Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Re: **Docket # 9P-1340/CP 1**

November 8, 1999

Dear Sir/Madam:

The petition that has been submitted by the **ENVIRONMENTAL HEALTH NETWORK**, P.O. Box 1155 . Larkspur, CA 94977, regarding Calvin Klein's Eternity, is wholeheartedly endorsed by the National Toxic Encephalopathy Foundation.

In 1991, the EPA produced a list of the 20 most common chemicals in 31 Fragrances that produced negative systemic effects. However, it is apparent that your agency has compromised it's own rules and regulations by **allowing** known toxins to be **willfully** utilized by the public without their **informed** consent. According to your own regulations (**21CFR 740.1, 740.2, 740.10 of the Federal Food, Drug and Cosmetic Act**);

21 CFR 74010

Subpart B—Warning Statements Sec. 740.10 Labeling of cosmetic products for which adequate substantiation of safety has not been obtained (a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is Page 201 misbranded unless it contains the following conspicuous statement on the principal display panel: Warning—The safety of this product has not been determined

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The gas **chromotography** results of Eternity demonstrate the **fact that** your **agency** is apparently not protecting the population **from** probable, long term, **unknown**, possibly fatal medical conditions **from** chemicals such as:

99P-1340

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A high percentage of chemicals used **in Eternity have not been thoroughly investigated** for the chemical, physical, and toxicological properties. This statement alone does not show prudence on your agency's part for the protection of the public **(Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)-**

Phenol, **2,6-bis(1, 1-dimethylethyl)-4-methyl-** Irritant, cancer **suspect agent, may cause reproductive /fetal effects**

Benzeneethanol is **listed** as; **Toxic, harmful by all routes, readily absorbed via skin, CNS effects**

A preponderance of **the** chemicals **in this** formula are irritants, it is a well documented **fact** that in 72% of asthmatics, they cite that perfume is a known trigger **that** induces a reaction, resulting in an asthma attack The percentage of children getting diagnosed with asthma is on the increase, to the extent that the first Lady **Hillary** Clinton is now involved **with this** travesty.

On January **22, 1999**, the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN), **Office** of Cosmetics and Colors, convened a public meeting to solicit input on priorities and strategies for its cosmetics program

'Division of Science and Applied Technology (DSAT) - Dr. D. Adele Dennis, Director, DSAT, described the role of her office and activities carried out by her staff. These included: providing chemical and toxicological support to the program through laboratory studies and **the development of analytical** methods for cosmetic products, ingredients and color additives, **conducting** scientific reviews on cosmetic policy issues, and responding to consumer complaints or injuries reported to the Center." Predicated on **this**, how can chemicals such as those listed above be allowed to be used without warnings of their dangers, if you have been unable to prove **their** safety?

'Dr. Bailey discussed highlights **from** the June 1998 CFSAN stakeholders meeting. Major themes that emerged for non-Food Safety Initiative programs included:

- Need to maintain a -credible FDA program to help ensure consumer confidence in cosmetic products.

- Need a solid, science-based program **staffed with highly** qualified scientists.

- Agency assistance to consumers and the regulated industry is important.

- Agency support of industry self-regulation programs such as the VCRP and the Cosmetic Ingredient Review is important."

The indoor air quality is considered more toxic than outside air according to the EPA. The potential for dangerous chemical interactions **from VOC's** used **in** cosmetics, building materials, cleaning products has not been **thoroughly** investigated by any independent laboratory.

The FDA has allowed the Cosmetic's industry to selfregulate. This is tantamount to the **free** reign to selectively protect itself under trademark secrets for utilization of

potentially dangerous chemicals (Methylene Chloride, **banned by your agency in 1988**, hazardous waste, known carcinogenic). This known carcinogenic is covered under trademark secrets and allowed to be introduced into **the** environment.

“Cosmetic, Toiletry, and Fragrance Association (CTFA) - Mr. Edward Kavanaugh, President, **CTFA**, presented five issues of concern:

- (1) **CFSAN** Resources and Enforcement - CTFA supports the restoration of resources by Congress and feels a strong FDA **enforcement** presence is needed. CTFA will continue to support additional funding for FDA but only **if the** cosmetic program remains in CFSAN. In 1997, there was a proposal to move **the** cosmetics program to FDA’s Center for Drug Evaluation and Research and CTFA was opposed to that plan. “

Who is running **the FDA, the** Cosmetics industry? **Their** watchdog group informing your agency they will support this act **if they** are not subjected to “Drug **Evaluation** and Research?

“(2) Cosmetic Ingredient Review (**CIR**) - The **CIR** was founded at the suggestion of FDA to evaluate the safety of cosmetic ingredients. The activities of **the CIR** are carried out under the same rules as FDA Advisory Committees. Mr. Kavanaugh feels the work of the **CIR** has saved FDA millions of dollars. In 1999, three significant changes are planned: “

This review committee is regulated by **the cosmetics industry**, this is not in the public’s best interest.

Senator Ted Kennedy introduced on the Senate floor September 10, 1997 the **following** excerpt:

The FDA reform **bill** puts the health and safety of every woman at risk-snip-. The cosmetic industry has borrowed a page **from** the **playbook** of the tobacco industry, by putting profits ahead of public health. Once again, a special interest lobby is using its **backroom** muscle in the Republican Congress to obtain an unconscionable advantage.

-snip-

A study by the respected, nonpartisan General Accounting Office reported that more than 125 ingredients available for use in cosmetics are suspected of causing cancer. Other cosmetics may cause adverse effects on the nervous system, including convulsions. Still other ingredients are suspected of causing birth defects. A carefully controlled study found that one in sixty users **suffered** a cosmetic related injury identified by a physician.

. The GAO **concluded** that “cosmetics are being marketed in the United States which may pose a serious hazard to **the** public.”

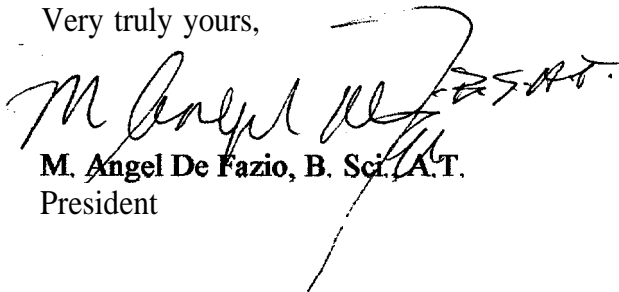
And these are only the acute injuries **that** require immediate medical care. The poisons in cosmetics can also cause long-term injuries and illnesses that do not develop

for years **after** exposure. We don't know the full extent of the possible damage, and this bill tells us we **can't** even warn the public of the dangers."

I have a very personal interest in having **these** so-called safe products properly labeled, as my **life** has been extremely restrictive because of such. I have been legally declared disabled with a primary diagnosis of Toxic **Encephalopathy** and a secondary disability of **asthma**. I am unable to return to medical school to **finish** my education to become a practitioner because of the systemic damage **from** such unregulated hazardous chemicals

In conclusion **the** factual data is available. The dangers and results of adverse exposure to known toxic chemicals must be addressed with the utmost diligence and urgency. Real people are being injured.

Very truly yours,

A handwritten signature in black ink, appearing to read "M. Angel De Fazio". The signature is fluid and cursive, with a long horizontal stroke extending to the right. To the right of the signature, the letters "B.S.A.T." are handwritten in a smaller, more upright script.

M. Angel De Fazio, B. Sci. (A.T.)
President

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